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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,470	04/06/2001	Richard W. Layne	1759.17208-FOR	6760
26308 7590 10/31/2007 RYAN KROMHOLZ & MANION, S.C. POST OFFICE BOX 26618 MILWAUKEE, WI 53226			EXAMINER NGUYEN, CAMTU TRAN	
			ART UNIT 3772	PAPER NUMBER
			MAIL DATE 10/31/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/828,470

Applicant(s)

LAYNE ET AL.

Examiner

Camtu T. Nguyen

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 12 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 12 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

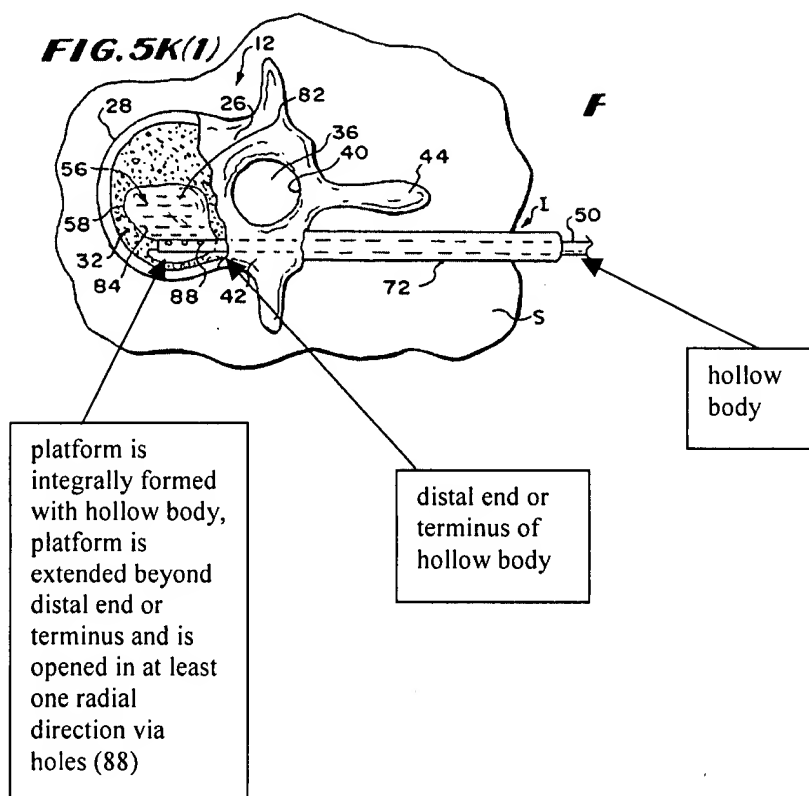
- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This Office Action is responding to applicant's amendment filed on 8/2/2007. Claim 1 has been amended. Claims 1, 4, 12, and 23 are pending.

Applicant's comments pertaining to the Reiley reference as acknowledged, particularly to the Reiley tool comprising all of the elements and features including a circumferentially enclosed hollow body but the Reiley tool does not teach an extension that protrudes beyond the distal terminus and forms a platform that is open in at least one radial direction. The Examiner respectfully disagrees. The Reiley et al discloses in Figures 1 and 2 a vertebral body (26) includes an exterior formed from compacted cortical bone (28) which encloses an interior volume (30) of cancellous bone (32). Figure 4 illustrates a tool (48) comprising a catheter tube (50) having a distal end (54) where at the distal end (54) carries an expandable body (56). Figure 5K(1) illustrates the catheter (50) introduced into the interior volume (30) occupied in the cancellous bone (32) and the expandable body (56) expanding on one side of the distal end of the catheter (50). With regards to independent claim 1 reciting an extension that protrudes beyond the distal terminus, thus, forming a platform, according to the specification on page 15 lines 6-7, the extension is the platform, structurally. In addition, the specification on page 15 lines 16-17 discloses the platform (220) could be formed integrally with the hollow member (210), thus, it is reasonable for one skilled in the art to interpret the Reiley's Figure 5k(1) as follows, which is consistent with applicant's specification.



The platform inherently serves as a barrier to inhibiting the expandable body (56) from expanding in more than one direction. Figure 7 illustrates the injector tip (90) occupying in cavity (84) while the expandable body (56) collapses and the injector tip (90) injects filler material into the cavity (84). With regards to claim 12, bone filling material, such as artificial bone substitute or flowable synthetic bone material or methyl methacrylate bone cement is known in the art of bone filling. For the reasons above, the Reiley reference is capable of performing method claims.

The Reiley reference applied in the previous Office Action stand rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Particularly, claim 1 amended to recite the tool comprising a circumferentially enclosed hollow body having a distal terminus, the tool also comprising an extension that protrudes beyond the distal terminus and forms a platform that is open in at least one radial direction. Such recitation is not consistent with the specification, as originally filed. Namely, page 15 lines 5-8 discloses an extension or platform protrudes from the distal end of the hollow member. In this particular embodiment, the platform comprises a semi-cylindrical section extending from the walls of the hollow member, the platform could be formed in different configurations as shown in Figure 28. Therefore, there is no disclosure support the circumferentially enclosed hollow body as recited in claim 1, there is no disclosure for the distal terminus as recited in claim 1, and no disclosure for the extension that protrudes beyond the distal terminus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 12, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Reiley et al (U.S. Patent No. 6,248,110). Reiley et al discloses in Figures 1 and 2 a vertebral body (26) includes an exterior forms from compacted cortical bone (28) which encloses an interior volume (30) of cancellous bone (32). Figure 4 illustrates a tool (48) comprising a catheter tube (50) having a distal end (54) where at the distal end (54) carries an expandable body (56). Figure 5K(1) illustrates the catheter (50) introduced into the interior volumn (30) occupied in the cancellous bone (32) and the expandable body (56) expanding on one side of the distal end of the catheter (50).. With regards to the platform, as recited, the Reiley et al the part at the distal end (54) where the suction holes (88) inherently serves as a barrier to inhibiting the expandable body (56) from expanding in more than one direction. Figure 7 illustrates the injector tip (90) occupying in cavity (84) while the expandable body (56) collapses and the injector tip (90) injects filler material into the cavity (84). The Reiley et al device would inherently perform steps recited in method claim 1. With regards to claim 12, bone filling material, such as artificial bone substitute or flowable synthetic bone material or methyl methacrylate bone cement is known in the art of bone filling.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3772

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CT Nguyen

Camtu Nguyen
October 18, 2007

Patricia Bianco
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10/24/07